Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

# General

## Title

Stroke: percent of acute ischemic stroke patients for whom IV t-PA was initiated at the hospital within 3 hours (less than or equal to 180 minutes) of time last known well.

## Source(s)

Specifications manual for national hospital inpatient quality measures, version 5.0b. Centers for Medicare & Medicaid Services (CMS), The Joint Commission; Effective 2015 Oct 1. various p.

# Measure Domain

## Primary Measure Domain

Clinical Quality Measures: Process

## Secondary Measure Domain

Does not apply to this measure

# Brief Abstract

## Description

This measure is used to assess the percent of acute ischemic stroke patients 18 years of age and older who arrive at the hospital within 2 hours of time last known well and for whom intravenous tissue plasminogen activator (IV t-PA) was initiated at the hospital within 3 hours of time last known well.

## Rationale

The administration of thrombolytic agents to carefully screened, eligible patients with acute ischemic stroke has been shown to be beneficial in several clinical trials. These included two positive randomized controlled trials in the United States (U.S.): the National Institute of Neurological Disorders and Stroke (NINDS) Studies, Part I and Part II. Based on the results of these studies, the U.S. Food and Drug Administration (FDA) approved the use of intravenous recombinant tissue plasminogen activator (IV r-TPA or t-PA) for the treatment of acute ischemic stroke when given within 3 hours of stroke symptom onset. A large meta-analysis controlling for factors associated with stroke outcome confirmed the benefit of IV t-

PA in patients treated within 3 hours of symptom onset. While controversy still exists among some specialists, the major society practice guidelines developed in the United States all recommend the use of IV t-PA for eligible patients. Physicians with experience and skill in stroke management and the interpretation of computed tomography (CT) scans should supervise treatment.

The European Cooperative Acute Stroke Study (ECASS) III trial indicated that intravenous r-TPA can be given safely to, and can improve outcomes for, carefully selected patients treated 3 to 4.5 hours after stroke; however, as the NINDS investigators concluded, the earlier that IV thrombolytic therapy is initiated, the better the patient outcome. Therefore, the target for IV t-PA initiation remains within 3 hours of time last known well. The administration of IV thrombolytic therapy beyond 3 hours of stroke symptom onset has not been FDA approved.

## Evidence for Rationale

Specifications manual for national hospital inpatient quality measures, version 5.0b. Centers for Medicare & Medicaid Services (CMS), The Joint Commission; Effective 2015 Oct 1. various p.

## Primary Health Components

Stroke; thrombolytic therapy; intravenous recombinant tissue plasminogen activator (IV r-TPA or t-PA)

## Denominator Description

Acute ischemic stroke patients whose time of arrival is within 2 hours (less than or equal to 120 minutes) of time last known well (see the related "Denominator Inclusions/Exclusions" field)

## Numerator Description

Acute ischemic stroke patients for whom intravenous (IV) thrombolytic therapy was initiated at the hospital within 3 hours (less than or equal to 180 minutes) of time last known well

# Evidence Supporting the Measure

## Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

A systematic review of the clinical research literature (e.g., Cochrane Review)

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

## Additional Information Supporting Need for the Measure

- Stroke ranks as the number five cause of death in the United States, following diseases of the heart, cancer, and chronic lung-related diseases. Each year, approximately 795,000 people experience a new or recurrent stroke. Approximately 610,000 of these are first attacks, and 185,000 are recurrent

strokes. These numbers equate to one stroke victim every 40 seconds on average. According to 2010 mortality data, one of every 20 deaths in the United States is attributable to stroke. Women have a higher lifetime risk of stroke than men. Lifetime risk of stroke among those 55 to 75 years of age was 1 in 5 for women (20% to 21%) and approximately 1 in 6 for men (14% to 17%). Blacks have a risk of first-ever stroke that is almost twice that of whites (American Heart Association [AHA], 2015).

- Stroke is also a leading cause of long-term disability (Centers for Disease Control and Prevention [CDC], 2009). Data from the National Heart, Lung and Blood Institute (NHLBI) revealed that 50% of ischemic stroke survivors age greater than 65 years had some hemiparesis; 35% experienced depressive symptoms; 30% were unable to ambulate without assistance; 26% were dependent in activities of daily living; 19% had aphasia; and 26% were institutionalized in a nursing home. The mean lifetime cost of ischemic stroke, including inpatient care, rehabilitation, and follow-up as necessary for residual deficits are estimated at $140,048 per person (AHA, 2015).
- Thrombolytic therapy is one of the most promising treatments for acute ischemic stroke. The majority of strokes are due to blockage of an artery in the brain by a blood clot. Prompt treatment with clot dissolving (thrombolytic) drugs can restore blood flow before major brain damage has occurred. In the United States (U.S.), Canada, and most European countries, alteplase/recombinant tissue plasminogen activator (rt-PA) has been approved for use within three hours of stroke symptom onset. Successful treatment is likely to improve neurological outcomes for ischemic stroke patients at three months and later; however, intracranial hemorrhage is a serious complication of therapy and may be fatal (Adams et al., 2007).
- Clinical practice guidelines for intravenous thrombolysis with rt-PA (Adams et al., 2007) cite the National Institute of Neurological Disorders and Stroke (NINDS) rt-PA Stroke Study (1995), which partially supported the approval of rt-PA by the U.S. Food and Drug Administration (FDA). The NINDS trial was conducted in two consecutive parts. Part A trials in the 1980s studied very low doses of thrombolytic therapy, given daily by intravenous route for several days. The onset of treatment occurred anytime from 5 to 14 days post symptom onset. Part A trials did not collect data on functional outcome. Part B trials from the 1990s and later used a single large dose of thrombolytic drug (80 to 100 mg rt-PA), given intravenously (IV) or intra-arterially (IA) within three, six, nine, or 24 hours of stroke. The primary end point in Part B of the study was a favorable outcome, defined as complete or nearly complete neurological recovery 3 months after stroke. Favorable outcomes were achieved in 31% to 50% of patients treated with rt-PA, as compared to 20% to 38% of patients given placebo (Kwiatkowski et al., 1999). The benefit was similar one year after stoke. The major risk of treatment was symptomatic intracranial hemorrhage which occurred in 6.4% of patients treated with rt-PA and 0.6% of patients given placebo (Marler et al., 2000).
- In 2008, European Cooperative Acute Stoke Study (ECASS)-3, a multi-center, prospective, randomized, placebo-controlled trial, studied the administration of rt-PA between three and 4.5 hours of stroke symptom onset (Hacke et al., 2008). The trial enrolled 418 patients treated with rt-PA per the current dosing guidelines (i.e., 0.9 mg/kg [maximum of 90 mg] with 10% given as an initial IV bolus and the remainder infused over one hour) and compared them with 403 who were given placebo. The frequency of the primary efficacy outcome (i.e., modified Rankin Scale score of 0 to 1 at 90 days after treatment) was significantly greater with rt-PA (52.4%) than with placebo (45.2%; odds ratio [OR] 1.34, 95% confidence interval [CI] 1.02 to 1.76; risk ratio 1.16, 95% CI 1.01 to 1.34; P=0.04). The point estimate for the degree of benefit seen in ECASS-3 (OR for global favorable outcome, 1.28, 95% CI 1.00 to 1.65) was less than the point estimate of benefit found in the pool of patients enrolled for 0 to 3 hours after stroke symptom onset in the NINDS study (OR 1.9, 95% CI 1.2 to 2.9).
- Currently, researchers, along with the field, continue to debate the risk of intracerebral hemorrhage with IV rt-PA in certain patient populations; however, the benefit of improved functional outcomes, and potential improvements in quality of life outweighs the decision to withhold treatment of the ischemia (Saposnik et al., 2012).
- Although the expanded timeframe of 3 to 4.5 hours for thrombolytic therapy was found to be effective for ischemic stroke patients and without significant increase in hemorrhagic events, the debate remains as to the benefit of the extended time frame. A treatment target of 3 hours remains the accepted recommendation as studies have shown the potential opportunity for improved

outcomes is greater with earlier treatment. Delays in evaluation and initiation of therapy for eligible patients with acute ischemic stroke should be avoided.

## Evidence for Additional Information Supporting Need for the Measure


Adams HP Jr, del Zoppo G, Alberts MJ, Bhatt DL, Brass L, Furlan A, Grubb RL, Higashida RT, Jauch EC, Kidwell C, Lyden PD, Morgenstern LB, Qureshi AI, Rosenwasser RH, Scott PA, Wijdicks EFM, American Heart Association, American Stroke Association Stroke Council, Clinical Cardiology Council. Guidelines for the early management of adults with ischemic stroke: a guideline from the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology [trunc]. Stroke. 2007 May;38(5):1655-711. [738 references] PubMed

American Heart Association (AHA). Heart disease and stroke statistics - 2015 update. Dallas (TX): American Heart Association (AHA); 2015. 22 p.

Centers for Disease Control and Prevention (CDC). Prevalence and most common causes of disability among adults--United States, 2005. MMWR Morb Mortal Wkly Rep. 2009 May 1;58(16):421-6. PubMed

Hacke W, Kaste M, Bluhmki E, Brozman M, Davalos A, Guidetti D, Larrue V, Lees KR, Medeghri Z, Machnig T, Schneider D, von Kummer R, Wahlgren N, Toni D, ECASS Investigators. Thrombolysis with alteplase 3 to 4.5 hours after acute ischemic stroke. N Engl J Med. 2008 Sep 25;359(13):1317-29. PubMed

Kwiatkowski TG, Libman RB, Frankel M, Tilley BC, Morgenstern LB, Lu M, Broderick JP, Lewandowski CA, Marler JR, Levine SR, Brott T. Effects of tissue plasminogen activator for acute ischemic stroke at one year. National Institute of Neurological Disorders and Stroke Recombinant Tissue Plasminogen Activator Stroke Study Group. N Engl J Med. 1999 Jun 10;340(23):1781-7. PubMed

Marler JR, Tilley BC, Lu M, Brott TG, Lyden PC, Grotta JC, Broderick JP, Levine SR, Frankel MP, Horowitz SH, Haley EC Jr, Lewandowski CA, Kwiatkowski TP. Early stroke treatment associated with better outcome: the NINDS rt-PA stroke study. Neurology. 2000 Dec 12;55(11):1649-55. PubMed

Saposnik G, Fang J, Kapral MK, Tu JV, Mamdani M, Austin P, Johnston SC, Investigators of the Registry of the Canadian Stroke Network (RCSN), Stroke Outcomes Research Canada (SORCan) Working Group. The iScore predicts effectiveness of thrombolytic therapy for acute ischemic stroke. Stroke. 2012 May;43(5):1315-22. PubMed


## Extent of Measure Testing

Unspecified

# State of Use of the Measure

## State of Use

Current routine use

## Current Use

not defined yet

# Application of the Measure in its Current Use

## Measurement Setting

Emergency Department

Hospital Inpatient

## Professionals Involved in Delivery of Health Services

not defined yet

## Least Aggregated Level of Services Delivery Addressed

Single Health Care Delivery or Public Health Organizations

## Statement of Acceptable Minimum Sample Size

Specified

## Target Population Age

Age greater than or equal to 18 years

## Target Population Gender

Either male or female

# National Strategy for Quality Improvement in Health Care

## National Quality Strategy Aim

Better Care

## National Quality Strategy Priority

Making Care Safer
Prevention and Treatment of Leading Causes of Mortality

# Institute of Medicine (IOM) National Health Care Quality Report Categories

## IOM Care Need

Getting Better

## IOM Domain

Effectiveness

Safety

Timeliness

# Data Collection for the Measure

## Case Finding Period

Discharges October 1 through June 30

## Denominator Sampling Frame

Patients associated with provider

## Denominator (Index) Event or Characteristic

Clinical Condition

Institutionalization

Patient/Individual (Consumer) Characteristic

## Denominator Time Window

not defined yet

## Denominator Inclusions/Exclusions

Inclusions
Discharges with an *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Principal Diagnosis Code* for ischemic stroke (as defined in the appendices of the original measure documentation)

Exclusions

- Patients less than 18 years of age
- Patients who have a Length of Stay (LOS) greater than 120 days
- Patients enrolled in clinical trials
- Patients admitted for *Elective Carotid Intervention* (as defined in the Data Dictionary)
- *Time Last Known Well* (as defined in the Data Dictionary) to arrival in the emergency department (ED) greater than 2 hours
- Patients with a documented *Reason For Extending the Initiation of IV Thrombolytic* (as defined in the Data Dictionary)
- Patients with a documented *Reason For Not Initiating IV Thrombolytic* (as defined in the Data Dictionary)

## Exclusions/Exceptions

not defined yet

## Numerator Inclusions/Exclusions

Inclusions
Acute ischemic stroke patients for whom intravenous (IV) thrombolytic therapy was initiated at the hospital within 3 hours (less than or equal to 180 minutes) of time last known well

Exclusions
None

## Numerator Search Strategy

Institutionalization

## Data Source

Administrative clinical data

Electronic health/medical record

Paper medical record

## Type of Health State

Does not apply to this measure

## Instruments Used and/or Associated with the Measure

- STK Initial Patient Population Algorithm Flowchart
- STK-4: Thrombolytic Therapy Flowchart

# Computation of the Measure

## Measure Specifies Disaggregation

Does not apply to this measure

## Scoring

Rate/Proportion

## Interpretation of Score

Desired value is a higher score

## Allowance for Patient or Population Factors

not defined yet

## Standard of Comparison

not defined yet

# Identifying Information

## Original Title

STK-4: thrombolytic therapy.

## Measure Collection Name

National Hospital Inpatient Quality Measures

## Measure Set Name

Stroke

## Submitter

The Joint Commission - Health Care Accreditation Organization

## Developer

The Joint Commission - Health Care Accreditation Organization

## Funding Source(s)

All external funding for measure development has been received and used in full compliance with The Joint Commission's Corporate Sponsorship policies, which are available upon written request to The Joint Commission.

## Composition of the Group that Developed the Measure

The composition of the group that developed the measure is available at: http://www.jointcommission.org/assets/1/6/Roster_STK_Maintenance_TAP_web_posting_Jul2012.pdf .

## Financial Disclosures/Other Potential Conflicts of Interest

Expert panel members have made full disclosure of relevant financial and conflict of interest information in accordance with the Joint Commission's Conflict of Interest policies, copies of which are available upon written request to The Joint Commission.

## Endorser

National Quality Forum - None

## NQF Number

not defined yet

## Date of Endorsement

2014 Dec 23

## Measure Initiative(s)

Physician Quality Reporting System

Quality CheckÂ®

## Adaptation

This measure was not adapted from another source.

## Date of Most Current Version in NQMC

2015 Oct

## Measure Maintenance

This measure is reviewed and updated every 6 months.

## Date of Next Anticipated Revision

Unspecified

## Measure Status

This is the current release of the measure.

This measure updates a previous version: Specifications manual for national hospital inpatient quality measures, version 4.3b. Centers for Medicare & Medicaid Services (CMS), The Joint Commission; 2014 Apr. various p.

## Measure Availability

Source available from The Joint Commission Web site . Information is also available from the QualityNet Web site . Check The Joint Commission Web site and QualityNet Web site regularly for the most recent version of the specifications manual and for the applicable dates of discharge.

## NQMC Status

The Joint Commission originally submitted this NQMC measure summary to ECRI Institute on April 30, 2009. This NQMC summary was reviewed accordingly by ECRI Institute on September 9, 2009. The information was verified by the measure developer on November 9, 2009.

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## Copyright Statement



# Production

## Source(s)

Specifications manual for national hospital inpatient quality measures, version 5.0b. Centers for Medicare & Medicaid Services (CMS), The Joint Commission; Effective 2015 Oct 1. various p.

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